K073704

# 510(k) SUMMARY
# J. Morita USA Inc.'s
# i-Dixel

## 1. Submitter Name and Address with Phone/Fax

| | |
|---|---|
| Registration No. 2081055 | Registration No. 3002807636 |
| Initial Distributor: | Manufacturer: |
| J. Morita USA, Inc. | J. MORITA MFG. CORP. |
| 9 Mason | 680 Higashihama Minami-cho |
| Irvine, CA 92618 | Fushimi-ku, Kyoto |
| USA | Japan 612-8533 |
| Telephone: 949-581-9600 | +81-75-611-2141 |
| Facsimile: 949-581-9688 | +81-75-605-2354 |

## 2. Contact Person

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

## 3. Date Summary Prepared

November 12, 2007

## 4. Device Name

| | |
|---|---|
| Trade or Proprietary Name: | i-Dixel |
| Common Name: | Image viewer software |
| Classification Name: | Picture archiving and communications system (21CFR892.2050) |
| Product Code: | LLZ |

## 5. Substantial Equivalency

Substantial equivalency is claimed against the following devices:

i-Dixel is practically the same as 3DX Integrated Information System, which is incorporated in our legally marketed device, 3D Accu-I-tomo XYZ Slice View Tomograph (K030450). i-Dixel is also presumably the same as N-Liten which is incorporated to ProMax 3D (Planmeca Oy, Finland).

## 6. Description of the Device

i-Dixel is a medical and dental diagnostic application for processing, archiving, and managing diagnostic images from multiple imaging modalities and other patient information. i-Dixel processes acquired 2D/3D images for diagnostic use.
Any patient record, name, ID, diagnosis, or image can be retrieved by simply clicking the mouse on the desired item in the easy-to-manage filing system made up of patient folders and their images.

i-Dixel is used in the medical environment and has the following functions as the entire system.

1) An image is acquired from X-ray equipment and saved in the database.
2) It saves data in the patient database besides the image.
3) Information in the image etc. saved in the patient data base can be seen.
4) It prints the image with applying information.
5) It makes maintenance of the patient database.
6) The image is imported and exported by various forms.
7) It is operated under the network environment.
8) It has the function of the input authentication by the password with operator ID to prevent patient's fault and data being lost by the operational mistake.
9) It is operated with 3D imaging modalities manufactured by J. Morita Mfg. Co.
10) It is operated with 2D imaging modalities or other panoramic/cephalometric x-ray device manufactured by J. Morita.
11) It can be connected with modalities which comply with TWAIN specifications.
12) It can incorporate images of device which is compatible to drivers including DixelD or 3DXD by J. Morita Mfg. Co.
13) It can import data from video camera.

## 7. Intended Use

i-Dixel can be used as viewer or database of medical imaging to support the diagnostic by medical imaging.

## 8. Safety and Effectiveness of the Device

i-Dixel is slightly revised version of 3DX Integrated Information System which is incorporated to FDA- cleared device (See below) in J. MORITA MFG. CORP.

Information of the device which 3DX Integrated Information System is incorporated:

| No. | Device | 510(k) number | Functions of the device | NOTE |
|---|---|---|---|---|
| 1 | 3D accu-i- tomo | K030450 | Dental x-ray computed tomography | 3D |

The i-Dixel is a slightly modified model from 3DX Integrated Information System but all changes are minor and don't pose any additional safety concerns. Safety characteristic has not changed between these two models and we judge these two software are substantially equal.

Consequently, it is self-explanatorily evident that this i-Dixel is substantially equivalent to 3DX Integrated Information System which is incorporated to 3D Accu-I-tomo XYZ Slice View Tomograph (K030450) in the sense of similar characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

FEB 21 2008

J. Morita USA, Inc.
% Mr. Keith A. Barritt
Attorney
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
WASHINGTON DC 20005

Re: K073704
Trade/Device Name: i-Dixel Image Viewer Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 28, 2007
Received: December 31, 2007

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(K) Number: ~~unknown~~ K073704

Device Name: i-Dixel

Indications for Use:

i-Dixel is a software for management of images obtained from x-ray imaging equipment and other imaging modalities. i-Dixel is used for medical and dental image examination and diagnosis.

The software is to be operated and used by doctor, dentists and other legally qualified professionals.

Prescription Use AND/OR Over-The-Counter Use

(Part21CFR801 Subpart D) (Part21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital,

Infection Control, Dental Devices

510(K) Number : K073704

Prescription Use ✓ OR Over-The-Counter Use

(Part21CFR801.109) (Optional Format 1-2-96)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number K073704